REMARKS

Status of the Claims

Prior to this amendment, claims 1-78 were pending and had been examined. Applicants have amended claims 71, 73, and 75 and added claims 79-84. Upon entry of this amendment, claims 1-84 will be pending and under prosecution. All of these amendments are fully supported by the specification and the claims as originally filed. No new matter has been added.

Claim Amendments

Applicants have amended claims 71, 73, and 75 to more particularly claim aspects of the invention. Applicants have also added claims 79-84 to more particularly claim certain aspects of the invention.

They are fully supported by the originally-filed specification. With regard to claim 71, support for the gel system comprising a gel chamber that comprises a gel, a cathode, and an anode in a sealed region of the chamber is supported in at least paragraph [0019] (page 4, lines 2-8) of the application. With regard to claim 73, support for the gel system comprising a gel chamber that comprises a gel, an anode, and a cathode in a sealed region of the chamber is supported in at least paragraph [0021] (page 4, lines 18-24) of the application. With regard to claim 75, support for the gel system comprising a gel chamber that comprises a gel, an anode, and a cathode in a sealed region of the chamber is supported in

at least paragraph [0024] (page 4, line 31 - page 5, line 5) of the application.

Newly added claims 79-84, drawn to electrolyte solutions that inhibit ion migration from the anode during electrophoresis, are also supported by the specification as filed, for example in at least paragraph [0055] (page 10, lines 22-32).

In view of the arguments and claim amendments presented herein, Applicants believe that the current claims are in condition for allowance. Reconsideration and withdrawal of the claims rejections are earnestly solicited.

Rejections Under 35 U.S.C. § 102(b)

Tocci (US Patent 3,715,295)

Claims 1-4, 16, 17, 27, 29, 30, 45-47, and 51 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Tocci (3,715,295). Applicants traverse this rejection for at least the following reasons.

Claims 1-4, 16, 17, 27, 29, and 30

Applicants assert that Tocci does not disclose a gel chamber that is sealed in at least one region, as set forth in independent claims 1, 16, and 27 and the claims dependant thereto. In contrast, the apparatus of claims 1, 16 and 27 and their dependant claims comprise a sealed region of a chamber.

In the Background of the Invention (page 2, lines 16-23), the Applicants state:

> [0010] Prior art electrophoresis systems are a potential source of contamination to the working environment in which the tests are performed. The two major sources of contamination are ethidium bromide and PCR products. Ethidium bromide is a hazardous chemical due to its mutagenic activity. In addition, the environment is a potential source of contamination to the system, since PCR is an extremely sensitive method. In fact, a single molecule of DNA product from one PCR (out of the trillions of molecules being produced) may interfere with the subsequent PCR such that it will produce incorrect results.

The claimed apparatus of claims 1, 16,27 and the dependant claims has overcome the problems with contamination associated with gel electrophoresis using a sealed region of the electrphoresis area. Paragraph 0046 of the specification states:

> It will be appreciated that Regions A or B or both of cassette 10 are totally sealed thereby reducing the possibility of contamination originating therefrom.

(emphasis added).

Thus the claimed apparatus is totally sealed in a manner that reduces contamination. Tocci does not teach a totally sealed region. Accordingly, Tocci does not anticipate the presently claimed invention.

A sealed region of a chamber of an apparatus of claims 1, 16, 27 and the dependants thereto is "totally sealed" to reduce the possibility of contamination from materials such as ethidium and DNA, both of which, when present, would be present in solution in the gel cassette and could otherwise leak or seep from the cassette.

The use of a sealed region of the electrophoresis chamber, however, presents special problems. Among other things, as the Examiner admits, water electrolysis generally occurs in typical gel electrophoresis chambers at "a sufficient voltage," which typically generates oxygen gas (Office Action, page 2). In a typical gel electrophoresis apparatus, such as the one disclosed in Tocci, the oxygen gas must be allowed to escape to avoid pressure buildup within the chamber. In fact, it is because of this generation of oxygen gas that the apparatus disclosed in Tocci can not be sealed.

Applicants submit that because Tocci does not teach or even suggest a totally sealed region of an electrophoresis chamber that comprises an electrode, as claims 1, 16, 27 and their dependants require, Tocci does not anticipate the currently claimed invention under U.S. § 102(b). Reconsideration and withdrawal of this rejection are earnestly solicited.

Claims 45-47 and 51

With regard to independent claim 45, Applicants assert that Tocci does not disclose an electrophoresis apparatus in which "at least one of said first electrode and said second electrode is embedded within said at least one body of the gel matrix" as set forth in claim 45. Applicants point out that in the present invention, a "body of gel matrix for facilitating electrophoresis" refers to a body of gel matrix that includes gel matrix areas for the separation of biomolecules. The claims' use of the phrase body of the gel matrix" is consistent with the specification as is seen in Figures 1-8, in which the

body of gel matrix is referred to as feature **18** of the figures. The use of "body of the gel matrix" is also explicit in paragraph [0054](page 10, lines 16-19), which refers to the lengthening the body of gel matrix **18** to prevent the interaction of migrating metal ions with the molecules to be separated:

> . . . the metal cations can be prevented from reaching the separated molecules by increasing the length of the body of gel matrix 18. This can be accomplished, for example, by increasing the length between the anode 24 and the loading sites 36.

In contrast to Tocci's system does not teach or suggest that the "electrode[s] [are] embedded within said at least one body of the gel matrix." Accordingly, Tocci does not anticipate claims 45-47 and 51 under 35 U.S.C. §102(b). Reconsideration and withdrawal of this rejection are earnestly solicited.

Pace (4,908,112)

Claims 1-6, 9, 15-17, 21, 27, 29-32, 37, 44-49, 51, 52, 71, and 72 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Pace (U.S. Patent 4,908,112). Applicants traverse this rejection for at least the following reasons.

Claims 1-6, 15-17, 27, 29-32, 37, and 44

Applicants assert that Pace does not anticipate claims 1-6, 15-17, 27, 29-32, 37, and 44, in that Pace does not teach an electrophoresis apparatus that comprises a body of gel matrix in a chamber that comprises at least one sealed region, in

which an anode, a cathode, or both are within the sealed region of the chamber.

Pace discloses a system for capillary electrophoresis that includes a semiconductor substrate having one or more channels micromachined through it. Pace provides at most two embodiments of the capillaru electrophoresis device, neither of which includes a chamber having sealed region that includes an electrode and a gel. One embodiment disclosed in Pace is a device for capillary electrophoresis, in which separation of biomolecules occurs in a liquid buffer medium, whereas all of the independent claims of the present application include a gel matrix that is used to separate molecules. Figure 4, referred to in the Office Action, is a schematic depiction of a device used for capillary electrophoresis in a liquid medium. This device does not include a body of gel matrix. The brief description of Figure 4 states: "FIG.4 is a schematic time representation of the manner in which the flow of liquids through the conduit of this invention is maintained." (column 5, lines 10-12).

The use of the microchannel separating device is described in Pace beginning at the bottom of column 8, line 65. Capillary electrophoresis through liquid media is described beginning at this point through column 9, line 37. Referring first to Figures 1-3, Pace states:

> The reservoirs 14 and 16 are first filled with buffer solution by injection the fluid into buffer reservoir 14 via an access hole (not shown) through the glass plate 38. Capillary action typically fills the conduits 10 and 20 within seconds . .

(column 8, line 66 - column 9, line 2; emphasis added)

Separation then occurs by migration of molecules through conduit 10:

> The detector signal is then recorded as a function of time, reflecting the movement of molecules through the conduit 10 . . .

(column 9, lines 17-19; emphasis added)

Thus, separation of molecules is occurring through buffer solution (capillary electrophoresis).

Pace then refers to the electrode arrangement depicted in Figure 4, in which electrode pairs are positioned within the conduit for staggered application of voltage across segments of the channel: " In the simplest case, a voltage may be applied between *the electrodes in the buffer* and the recipient chambers to drive the electrophoresis." (column 9, lines 35-37, emphasis added.) Thus, the apparatus of Figure 4 does not include a body of gel matrix as set forth in claims 1, 16, and 27.

In a different embodiment Pace discloses a device that includes gel electrophoresis within a microchannel. Pace refers to Figures 7 and 8 in discussing this gel electrophoresis embodiment (column 9, line 38 through column 10, line 20) which includes buffer reservoirs that connect to the channel in which electrophoresis occurs. In this description, he explicitly states that "The reservoir is left *open to the atmosphere*. An electrode 98 is formed on the surface of the reservoir and extends over to a bond pad 100". (column 9, lines 59-61). This arrangement is seen clearly in Figures 8A, 8B, and 8C, in which a channel (92) that contains gel is connected via a hole (102)

to the reservoir (96) etched in the glass cover. The electrode (98) is on the surface of the reservoir, completely external to the channel that contains the gel and exposed to the atmosphere. Thus, Pace does not disclose a gel electrophoresis apparatus system having a chamber that includes a sealed region that includes an anode or a cathode.

Because Pace does not disclose an apparatus that comprises a chamber that includes a body of gel matrix and at least one sealed region, in which a sealed region includes a cathode or an anode, all of the elements of claims 1, 16, and 27 are not disclosed by Pace. Accordingly, Pace does not anticipate claims 1-6, 15-17, 27, 29-32, 37, and 44 under U.S.C. § 102(b). Reconsideration and withdrawal of this rejection are earnestly solicited.

Claims 45-49, 51, and 52

Claim 45 sets forth an electrophoresis apparatus in which "at least one of said first electrode and said second electrode is embedded within said at least one body of gel matrix". Pace does not disclose an electrode embedded within a body of gel matrix.

As detailed herein, Pace describes two distinct embodiments for electrophoresis in a microchannel device, neither of which includes electrodes embedded within a gel matrix. Accordingly, Pace does not anticipate claims 45-49, 51 and 52 under 35 U.S.C. §102(b). Reconsideration and withdrawal of this rejection are earnestly solicited.

Claims 71 and 72

Claims 71 and 72 have been rejected as allegedly anticipated by Pace under §102(b). This rejection is respectfully traversed. Without agreeing with the Examiner's assertions that Pace anticipates claims 71 and 72, Applicants have amended claim 71 to better capture envisioned commercial embodiments. Claim 71 and its dependant claims now recite an apparatus that comprises a gel, in which the gel is within a chamber that comprises a sealed region, and the chamber also comprises an anode contained within said sealed region and a cathode in contact with said gel matrix. In view of the amendments to the claims, the Examiner's rejection of claims 71 and 72 as anticipated by Pace is now moot. Reconsideration and withdrawal of this rejection are earnestly solicited.

Rejections Under 35 U.S.C. § 103(a)

Tocci and Pace

Claims 5, 6, 31, 32, 48, 49, and 51 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Tocci in view of Pace. Applicants traverse this rejection. The Office Action maintains in the rejection that Tocci discloses an electrophoresis unit as described in addressing claims 4, 30, 45, and 47. Applicants have already argued in a previous section of this response responding to a §102(b) rejection that Tocci does not disclose an electrophoresis apparatus having a chamber that includes at least one sealed region and a gel matrix, and has an anode in the sealed region (claims 5 and 6) or a cathode in the sealed region (claims 31 and 32). In particular, Applicants respectfully disagree that Tocci

provides disclosure of an electrophoresis apparatus that includes a gel matrix chamber that has a sealed region. Applicants have also argued in a previous section of this response responding to a §102(b) rejection that Pace does not disclose an electrophoresis apparatus having a gel matrix chamber that includes at least one sealed region that includes an electrode, and therefore Pace does not make up for the deficiencies of Tocci. Thus, the requirement of 35 U.S.C. §103(a) that each and every claim element be taught or suggested by the combination of cited references is not met for claims 5, 6, 31, and 32. Reconsideration and withdrawal of this rejection are earnestly solicited.

With regard to claims 48, 49, and 51, Applicants have also argued in a previous section of this response responding to the §102(b) rejection of these claims that Tocci does not disclose an electrophoresis apparatus having an electrode embedded in a body of gel matrix. Pace also does not disclose an electrophoresis apparatus having an electrode embedded in a body of gel matrix, for the reasons provided in the response to the §102(b) rejection of claims using Pace. Thus, the requirement of 35 U.S.C. §103(a) that each and every claim element be taught or suggested by the combination of cited references is not met for claims 48, 49, and 51. Reconsideration and withdrawal of this rejection are earnestly solicited.

Tocci and Eibl

Claims 7-9, 33, 34, and 50 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Tocci in view of

Eibl. Applicants traverse this rejection. Claims 7-9, 33, and 34 all incorporate the feature of for an electrophoresis chamber having a sealed region that includes an electrode. Applicants have demonstrated that Tocci does not contain each and every limitation of the claimed invention, and Eibl does not cure these deficiencies. Neither Tocci nor Eibl, alone or in combination, teach or suggest an electrophoresis apparatus having a gel matrix chamber that includes at least one sealed region that includes an electrode. With regard to claim 50, Tocci does not disclose an electrode embedded within a body of gel matrix and Eibl does not cure this deficiency. Thus, for claims 7-9, 33, 34, and 50, each and every recited claim is not taught or suggested in the cited references, and the requirements for rejection under 35 U.S.C. §103(a) are not met. Reconsideration and withdrawal of this rejection are earnestly solicited.

Pace and Eibl

Claims 7, 8, 33, 34, and 50 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Pace in view of Eibl et al. Applicants have addressed the lack of disclosure in Pace of an electrophoresis apparatus having a gel matrix chamber that includes at least one sealed region that includes an electrode in the section responding to the 35 U.S.C. §102 (b) rejection. Claims 7, 8, 33, and 34 incorporate this feature. Eibl does also does not disclose a gel matrix chamber that includes at least one sealed region that includes an electrode. Thus, each and every element of claims 7, 8, 33, and 34 are not taught or suggested by the references. Claim 50 incorporates the feature of an electrode embedded in the gel

matrix. As argued above, Pace does not disclose an electrode embedded in a gel matrix, and neither does Eibl. Thus, each and every element of claim 50 is not taught or suggested by the references. The requirements for rejections under 35 U.S.C. §103(a) therefore are not met. Reconsideration and withdrawal of this rejection are earnestly solicited.

Tocci and Flesher

Claims 19-21, 35, and 36 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Tocci in view of Flesher et al. Applicants traverse this rejection.

Applicants disagree that Tocci discloses the apparatus set forth in claims 16 and 27, from which the rejected claims depend, for the reasons provided in the section responding to the 35 U.S.C. §102(b)rejection using Tocci. Flesher does not make up for the deficiencies of Tocci. Therefore, Tocci and Flesher, alone or in combination, do not teach or suggest all the elements of the rejected claims. Reconsideration and withdrawal of this rejection are earnestly solicited.

Pace and Flesher

Claims 19, 20, 35, and 36 stand rejected under as allegedly being unpatentable under 35 U.S.C. §103(a) over Tocci in view of Flesher et al. Applicants traverse this rejection.

Applicants respectfully disagree that Pace discloses the apparatus set forth in claims 16 and 27, from which the rejected claims depend, for the reasons provided in the section responding to the 35 U.S.C. §102(b)rejection referencing Pace.

Flesher does not make up for the deficiencies of Pace. Therefore, Pace and Flesher, alone or in combination, do not teach or suggest all the elements of the rejected claims. Reconsideration and withdrawal of this rejection are earnestly solicited.

Tocci and Elson

Claims 10, 11, 22, 23, and 38-40 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Tocci in view of Elson et al. Applicants traverse this rejection.

Applicants disagree that Tocci discloses the apparatus set forth in claims 16 and 27, from which the rejected claims depend, for the reasons provided in the section responding to the 35 U.S.C. §102(b)rejection referencing Tocci. Elson does not make up for the deficiencies of Tocci. Therefore, Tocci and Elson, alone or in combination, do not teach or suggest all the elements of the rejected claims. Reconsideration and withdrawal of this rejection are earnestly solicited.

Tocci, Elson, and Day

Claims 12-14, 24-26, and 41-43 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Tocci in view of Elson et al and further in view of Day. Applicants traverse this rejection.

Applicants disagree that Tocci discloses the apparatus set forth in claims 1, 16 and 27, from which the rejected claims depend, for the reasons provided in the section responding to the 35 U.S.C. §102(b)rejection referencing Tocci. Neither Elson

nor Day make up for the deficiencies of Tocci. Therefore, Tocci, Elson, in Day, alone or in combination, do not teach or suggest all the elements of the rejected claims. Reconsideration and withdrawal of this rejection are earnestly solicited.

Tocci, Pace, and Monthony

Claims 53-56 and 62-65 stand rejected under 35 U.S.C. §103(a) as unpatentable over Tocci in view of Pace and Monthony et al. Applicants traverse this rejection.

As argued in the section responding to the 35 U.S.C. §102(b)rejection referencing Tocci, Tocci does not disclose a device having a chamber that includes a body of gel matrix and at least one electrode embedded in the body of gel matrix. Pace does not make up for the deficiencies of Tocci, as detailed in the arguments against the 102(b) rejection referencing Pace. Monthony also does not remedy the absence of the features lacking in Tocci. Therefore, Tocci, Pace and Monthony, alone or in combination, do not teach or suggest all the elements of the rejected claims. Reconsideration and withdrawal of this rejection are earnestly solicited.

Tocci, Pace, Monthony, and Elson

Claims 57 and 66 stand rejected under 35 U.S.C. §103(a) as unpatentable over Tocci in view of Pace, Monthony et al., and Elson et al. Applicants traverse this rejection.

As argued in the section responding to the 35 U.S.C. §102(b)rejection referencing Tocci, Tocci does not disclose a

device having a chamber that includes a body of gel matrix and at least one electrode embedded in the body of gel matrix. Pace does not make up for the deficiencies of Tocci, as detailed in the arguments against the 102(b) rejection referencing Pace. Monthony and Elson also do not remedy the absence of the features lacking in Tocci. Therefore, Tocci, Pace, Monthony, and Elson, alone or in combination, do not teach or suggest all the elements of the rejected claims. Reconsideration and withdrawal of this rejection are earnestly solicited.

Tocci, Pace, Monthony, Elson, and Day

Claims 58-60 and 67-69 stand rejected under 35 U.S.C. §103(a) as unpatentable over Tocci in view of Pace, Monthony et al., and Elson et al., and further in view of Day. Applicants traverse this rejection.

As argued in the section responding to the 35 U.S.C. §102(b)rejection referencing Tocci, Tocci does not disclose a device having a chamber that includes a body of gel matrix and at least one electrode embedded in the body of gel matrix. Pace does not make up for the deficiencies of Tocci, as detailed in the arguments against the 102(b) rejection referencing Pace. Neither Monthony et al., nor Elson et al., nor Day remedy the absence of the features lacking in Tocci. Therefore, Tocci, Pace, Monthony et al., Elson et al., or Day, alone or in combination, do not teach or suggest all the elements of the rejected claims. Thus, claims 58-60 and 67-69 are nonobvious under 35 U.S.C. §103(a). Reconsideration and withdrawal of this rejection are earnestly solicited.

Pace and Monthony

Claims 53-57, 61-66, 70, 77,and 78 stand rejected under as being unpatentable under 35 U.S.C. §103(a) over Pace in view of Monthony et al. Applicants traverse this rejection.

Regarding claims 53-57, 61-66 and 70, Applicants disagree that Pace discloses or suggests the apparatus set forth in claims 53, 62, from which the rejected claims depend, for the reasons provided in the section responding to the 35 U.S.C. §102(b)rejection referencing Pace. Flesher does not make up for the deficiencies of Pace. Monthony does not remedy the deficiency of Pace. Therefore, Pace and Monthony, alone or in combination, do not teach or suggest all the elements of the rejected claims. Reconsideration and withdrawal of this rejection are earnestly solicited.

Regarding claims 77 and 78, amended claim 75, from which these claims depend, has been amended such that the gel apparatus used in the method such that the chamber includes a gel and a two sealed regions, each of which comprises an electrode. Neither Pace nor Monthony teach or suggest these features. Thus all of the claim limitations are not taught or suggested by Pace and/or Monthony. Reconsideration and withdrawal of this rejection are earnestly solicited.

Double Patenting

Applicants note that claims 18, 28, 71-76 and 77-78 have been rejected under the judicially created doctrine of obviousness-type double patenting. Applicants respectfully disagree with the Examiner's assertions that the rejected

claims are obvious in view of the cited references; however, Applicants will address the Examiner's arguments, upon indication of otherwise allowable subject matter.

CONCLUSION

Applicants respectfully submit that all of the pending claims are in form for allowance. If the Examiner believes, however, that any matters remain outstanding, applicants respectfully request that the Examiner call the undersigned.

Respectfully submitted,

Date September 15, 2005 By _____

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CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being facsimile transmitted to the USPTO or being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 15th day of September, 2005

_____ _____
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